

4.0 EO residuals for sterile iodophor products

Topical antiseptics indicated for use as a patient preoperative skin preparation are most often contained in kits with sponges or other application devices. These kits are typically sterilized before use and most typically by ethylene oxide (EO) processing. If an antiseptic product contains iodine and is sterilized via EO there is a potential for ethylene iodohydrin formation. Ethylene iodohydrin is a known skin irritant created upon the reaction of iodine with ethylene oxide. Container closure systems sterilized by EO for products containing iodine need to be designed to minimize this occurrence. Since the FDA has published limits for ethylene chlorhydrin, we feel that the TFM should provide limits for the analogous ethylene iodohydrin concentration allowed in products that do not provide an absolute EO barrier to the iodine-containing component.